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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/887,507 | 06/22/2001 | Norio Miura | KIP 002 | 5780 |

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| EXAMINER | |
|---|---|
| CHIN, CHRISTOPHER L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | |

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/887,507 | MIURA ET AL. | |
| | Examiner | Art Unit | |
| | Christopher L. Chin | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/887,007

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/6/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite. The third step recites preparing an antibody that is coupled to the fixed protein conjugate but then another solution of the same antibody is also contacted with the fixed protein conjugate. These steps appear to be redundant. The recitation of "in a specific manner" is also not clear as to how the antibody has been prepared. The fourth step is further vague because the prepared sample contains more of the same antibody that has been coupled to the protein antigen on the resonance material in the third step. The function of the antibody for measuring the medical substance is not clearly defined since some of the antibody is coupled to the fixed protein conjugate while other antibodies are in solution according to steps three and four.

Claim 6 is vague and indefinite. In the last 2 lines of the claim, the recitation of "which is almost identical to that of the medical substance" is not clear as to how identical the protein antigen is to the medical substance.

Claim 7 is vague because it does not recite any limitations that would further limit the components of the apparatus recited in claim 6. The "change to be detected by said

detecting means" defined in the claim does not further limit the apparatus being claimed.

Claims 8-10 suffer from the same deficiency as claim 7. Claims 8-10 define the "change to be detected" which does not further limit the apparatus being claimed.

Claim 12 is vague. In line 5, the recitation of "which is almost identical to that of the medical substance" is not clear as to how identical the protein antigen is to the medical substance.

Claim 15 is vague. In lines 4-5, the recitation of "which is almost identical to that of the medical substance" is not clear as to how identical the protein antigen is to the medical substance.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 6-13 and 15-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23

and 26-27 of copending Application No. 08/985,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending '007 claims an apparatus with essentially the same limitations as the instantly claimed apparatus.

Copending '007 claims an apparatus for measuring a medical substance in a sample comprising:

a resonance phenomenon generating section having a resonance material;

a detecting means for detecting a change of an incident light which is made incident upon said resonance material to generate said resonance phenomenon or a change of a reflected light thereof; and

wherein the medical substance to be measured is fixed to said resonance material as an antigen.

Copending '007 differs from the instant invention in not defining the conjugated protein antigen fixed to the resonance material as being almost identical to that of the medical substance that is to be detected.

However, it would have been obvious to one of ordinary skill in the art that the antigen in the apparatus of copending '007 is almost identical to the medical substance that is to be detected because copending '007 refers to the antigen as the medical substance which is the same medical substance that is to be detected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 6 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Partin et al.

Partin et al (U.S. Patent 5,082,630) discloses a fiber optic detector for immuno-testing. The detector functions by attachment of antibodies to the distal end of an optical fiber or waveguide and saturating the antibodies with fluorescently-tagged antigens (i.e. conjugated protein antigen). When exposed to an air sample, a decrease in fluorescence indicates the presence of the suspect chemical compound in the air sample. The fluorescently-tagged antigen is displaced by the airborne compound specific for the antibodies. Cocaine and heroin (i.e. medical substances) can be detected as the airborne compound (col. 2, lines 48-67).

6. Claims 6-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al.

Charles et al (WO 90/11525) discloses a surface plasmon resonance sensor for performing a displacement immunoassay. The sensor comprises a metallic layer on a block of material that is transparent to electromagnetic radiation. Antibodies specific for analyte are immobilized to the metallic layer. Analyte analogue molecules are reversibly

bound to the antibodies. The presence of analyte will displace the analyte analogues from the antibodies. The analyte analogues will be as near as possible or even completely identical to the analyte (page 3). The disclosed sensor can measure the rate of change of reflectivity and/or the absolute reflectivity at a given time (page 6).

With respect to claims 7-10, these claims recite limitations directed to that the apparatus is supposed to detect (i.e. an intended use) and thus are not considered actual limitations of the apparatus.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6-13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batchelder et al in view of Charles et al.

Batchelder et al (U.S. Patent 4,844,613) discloses an optical surface plasmon sensor. The sensor comprises a transparent prism which supports a glass slide and a layer of conductive metal, typically gold, on the glass slide. The layer of conductive metal is coated with antibodies for biosensing applications. Typically, the sensitivity of the sensor is such that a change in the antibody layer thickness causes a change of 0.01 degrees in the resonance angle for a source wavelength of 820 nm (col. 2, lines 18-64).

Batchelder et al differs from the instant invention in failing to teach immobilizing a conjugated protein antigen onto the conductive metal layer.

See above for the teachings of Charles et al.

It would have been obvious to one of ordinary skill in the art to modify the sensor of Batchelder et al with a conjugated protein antigen, as taught by Charles et al, for displacement immunoassays because the sensor of Batchelder et al is disclosed for biosensing applications and Charles et al shows that displacement immunoassays can be performed on surface plasmon resonance sensors such as the sensor of Batchelder et al.

With respect to claims 7-10, these claims recite limitations directed to that the apparatus is supposed to detect (i.e. an intended use) and thus are not considered actual limitations of the apparatus.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher L. Chin

Christopher L. Chin
Primary Examiner
Art Unit 1641
6/18/04

6/18/04